

REMARKS

In an effort to expedite prosecution, Applicant have canceled claims 1-8, 12-17, 22-25, and 27 and amended claim 9 to be directed to method of treating a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation in a patient in need thereof comprising the step of topically administering an effective amount of a semi-solid composition formulated for topical administration, said composition consisting essentially of a purified polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutically acceptable carrier, wherein said polyunsaturated fatty acid fraction consists of polyunsaturated fatty acids AND is free of *Nigella sativa* L. saturated fatty acids, sterols, volatile oils, and glyceryl esters. Support for the newly added limitations are found in now canceled claims15 (“wherein the polyunsaturated fatty acid fraction consists essentially of polyunsaturated fatty acids”) and claim 27 (“wherein the polyunsaturated fatty acid fraction is free of *Nigella sativa* L. saturated fatty acids, sterols, volatile oils, and glyceryl esters). Thus, Applicant submits that no new matter has been added. However, Applicants reiterate that this amendment is presented solely for the purpose of expediting prosecution and should not be construed as Applicants’ agreement with or acquiescence to the grounds of rejection previously set forth.

Pursuant to the entry of the instant amendment, claims 9-11, 18-21, 26, 28, and 29 are presently pending. Applicant respectfully submits that all claims to non-elected inventions have been canceled and thus all of the presently pending claims read on the elected invention of Group II, directed to a method of treating a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation with a semi-solid composition formulated for topical administration comprising a purified polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutical carrier.

Applicant respectfully submits that the instant response renders moot the outstanding claim rejections and places the instant application in condition for allowance. Further to this position, Applicant submits the following remarks:

Double Patenting Rejections

Claims 9, 11, and 15 stand provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-7 and 11 of copending Application No. 12/043,052. While Applicant respectfully disagrees with the Examiner's characterization of the claims, in an effort to expedite prosecution, Applicant submits herewith a terminal disclaimer over co-pending Application No. 12/043,052, thereby rendering moot the outstanding double patenting rejection.

Rejections under 35 U.S.C. § 103

Ahmad in view of Berg:

Claims 9-11, 15, 18-21, and 26 stand finally rejected under 35 U.S.C. § 103(a) as being obvious over Ahmad et al. (US 2005/0058735) in view of Berg (Advances in Dermatology, 1988). The Examiner maintains that "it would have been obvious to one of ordinary skill in the art to use *Nigella sativa*, a member of the Ranunculaceae [family], for the treatment of diaper rash since Ahmad teaches that members of Ranunculaceae can be used for the treatment of skin diseases and given that Berg teaches that diaper rash is a skin disease."

For reasons of record, Applicant continues to dispute the Examiner's suggestion that Ahmad connects *Nigella sativa* extracts with the topical treatment of skin infections. However, recognizing that the Examiner appears to be fixed in her position and in an effort to expedite prosecution, Applicant has herewith amended independent claim 9 to not only require the step of topically administering an effective amount of a semi-solid composition formulated for topical administration that consists essentially of a purified polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutically acceptable carrier, but further have required that the polyunsaturated fatty acid fraction consist of polyunsaturated fatty acids and be free from other contaminants, namely *Nigella sativa* L. saturated fatty acids, sterols, volatile oils, and glyceryl esters.

As noted previously, Ahmad discloses the use of crude extracts, i.e., ground plant material extracted in a polar solvent and subsequently vacuum concentrated (see Ahmad at paragraphs [0065] and [0129]). As such, Ahmad's botanical extract is comprised of numerous components, including fatty acids, glyceryl esters, volatile oils, and total sterols (see Applicant's Figure 1), components expressly excluded from the purified polyunsaturated fatty acid fraction

of claim 9 as presently amended. Furthermore, in that Ahmad fails to further characterize the extract and/or identify the one or more “medicinal contents” responsible for the desired activity (i.e., immunomodulation), there can be teaching or suggestion in the reference of selecting only the polyunsaturated fatty acid components to the exclusion of all others. While Applicant does not dispute that processes for selectively enriching an extract in polyunsaturated fatty acids were known at the time of invention, Applicant reiterates that none of the prior art references disclose the desirability of such enrichment. Thus, Applicant submits that neither Berg nor Schlenk nor Ali nor any other reference of record cures the primary deficiency of Ahmad.

On the issue of the transitional phrase "consisting essentially of", it is well settled that "a 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). In the context of the presently pending claims, Applicant respectfully submit that the "consisting essentially of" phrase limits the scope of the claims to the specified material (i.e., purified polyunsaturated fatty acids) "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention" (i.e., materials that affect or interfere with bioactivity of polyunsaturated fatty acids of *Nigella sativa* in the treatment pathological skin conditions¹). *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). Thus, Applicant respectfully submits that while the claimed semi-solid composition "consisting essentially of" a purified polyunsaturated fatty acid fraction consisting exclusively of polyunsaturated fatty acids allows for the inclusion of conventional pharmaceutical additives, such as emulsifiers, stabilizers, and preservatives, it requires that the purified polyunsaturated fatty acid be the sole pharmaceutical agent active in the treatment of a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation in a patient.

¹ Applicant's specification at page 9, line 7: "Without intending to be bound by any theory of the invention, the compositions of the present invention act as an antihistamine and regulate skin cell membrane functions, including modulating trans-epidermal water loss. . . [to] produce eicosanoids. . . important hormone-like compounds dampen inflammatory reactions in the skin."

Thus, Applicant respectfully submits that the prior art of record fails to disclose or suggest the use of a semi-solid composition formulated for topical administration consisting essentially of a purified *Nigella sativa* polyunsaturated fatty acid fraction that consists only of polyunsaturated fatty acids and expressly excludes other *Nigella* components such as saturated fatty acids, sterols, volatile oils, and glyceryl esters in the treatment of a skin condition arising from fungal infection, bacterial infection, allergic reaction, or inflammation. Accordingly, Applicant respectfully submits that the invention of the claims as amended herewith is novel and non-obvious over the cited prior art of record and respectfully requests reconsideration and withdrawal of the outstanding rejections under 35 U.S.C. § 103(a) in view of the amendments and remarks herein.

Ahmad in view of Berg & Nickavar:

Claims 28-29 stand finally rejected under 35 U.S.C. § 103(a) as being obvious over Ahmad et al. (US 2005/0058735) in view of Berg (Advances in Dermatology, 1988) and Nickavar (Naturforsch, 2003). For reasons of record, Applicant respectfully submits that the Nickavar reference fails to cure the above-noted deficiencies of Ahmad and Berg with respect to independent claim 9 as amended herewith. Thus, in that the cited references, alone or in combination, fail to suggest the invention of the pending claims, Applicant respectfully submits that the conclusion of obviousness is in error. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 28-29 under 35 U.S.C. § 103(a) in view of the amendments and remarks herein.

Ahmad in view of Berg, Schlenk, and Ali:

Claim 27 stands finally rejected under 35 U.S.C. § 103(a) for being obvious over Ahmad et al. (US 2005/0058735) in view of Berg (Advances in Dermatology, 1988), Schlenk et al. (JACS, 1950), and Ali et al. (PTR, 2002). Applicants respectfully submit that this rejection is rendered moot by the cancellation of claim 27.

CONCLUSION

The outstanding Office Action set a three-month shortened statutory period for response. Pursuant to the entry of Applicant's petition for a one month extension of time, response is due on or before **March 9, 2009**. Accordingly, Applicant submits that this response is timely and that no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to the undersigned's Deposit Account No. **50-2101**.

If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,

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